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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,279	07/08/2003	Richard Harkins	51791AUSD1	4679

27586 7590 04/01/2005

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,279

Applicant(s)

HARKINS ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-29, 31-41 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 24-29, 31-41, and 44-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment received July 8, 2003 is acknowledged.

Claims 1-23, 30, and 42-43 have been cancelled.

Claims 29 and 41 have been amended.

Claims 44-46 have been added.

Claims 24-29, 31-41, and 44-46 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 24-29, 31-34, and 44, drawn to antibodies and immunoconjugates, classified in class 530, subclass 387.1.
 - II. Claim 35, drawn to a method of selectively destroying a cell, classified in class 435, subclass 7.21.
 - III. Claim 36, drawn to a method of treating a disease with an immunoconjugate, classified in class 424, subclass 134.1.
 - IV. Claim 37, drawn to a method of treating a disease by administering a ribozyme, classified in class 536, subclass 24.5.
 - V. Claim 38, drawn to a method of treating a disease by administering a polynucleotide, classified in class 536, subclass 23.1.

- VI. Claims 39-40, drawn to a diagnostic method to detect polypeptides, classified in class 435, subclass 7.1.
- VII. Claim 41, drawn to a diagnostic method to detect polynucleotides, classified in class 435, subclass 7.6.
- VIII. Claim 45, drawn to a polypeptide vaccine, classified in class 424, subclass 185.1.
- IX. Claim 46, drawn to a DNA vaccine, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II/III/VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies and immunoconjugates of Group I can be used in any of the methods of Groups II, III, or VI.

4. Inventions I, VIII, and IX are different products. These products differ in their structure. These differences allow for one product to be more suitable for a certain application, such as a specific therapeutic or diagnostic method, than another product of the instant invention. Further, art that anticipates any one of these products would not

necessarily anticipate or render obvious the invention of the other Groups. Therefore they are patentably distinct.

5. Inventions II-VII are different methods. As such they recite different process steps, require unique ingredients that differ in their structure, such as antibodies, ribozymes, nucleic acids and peptides, and achieve divergent goals such as therapeutic treatment or diagnosis of a disease state. Any particular method of diagnosis would not necessarily anticipate nor render obvious any other diagnostic method or any method of treatment, with the same applying to any particular therapeutic method. Therefore the methods of the instant invention are patentably distinct.

6. The products of Groups VIII/IX are not indicated as being useful in performing the methods of Groups II-VII, and these methods do not make the products of the indicated groups. The same relationship holds for the products of Group I and the methods of Groups IV, V and VII. Therefore, the inventions of these groups are patentably distinct.

7. Because these inventions are distinct for the reasons given above, and the literature searches required for Groups I-IX are not coextensive because art that reads on any one of the above Groups would not necessarily anticipate nor render obvious the invention of any other Group, and Groups I-IX have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to patentably distinct species of the claimed inventions of Groups I-IX. These species are the specific epitope/sequence of the polypeptide of SEQ ID NO:2 that is to be used in the inventions of Groups I-IX. Applicant is required to elect a single defined sequence for the purpose of an initial art examination. Examples of an appropriate response to this species election are "amino acid 188 to amino acid 210 of SEQ ID NO:2", or "SEQ ID NO:8". Note that election of SEQ ID NO:2 without indicating a specifically defined amino acid subsequence will be viewed as a nonresponsive election.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 24, 29, 31-34 of Group I, and all claims of Groups II-IX are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

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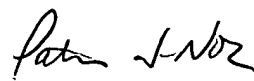
where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 25, 2005


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